UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT LAWTON, THOMAS PATRICK O'CONNOR, JR., BARBARA ANN BARTOL, and PAUL SCOTT M^AC^HENRY

Appeal No. 2005-2708
Application No. 09/765,739

HEARD: November 17, 2005

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 21-24 and 39-42. Claims 1-20, and 25-34 have been withdrawn from consideration by the examiner and/or appellants, but remain pending. Paper No. 18. Claims 35-38 have been canceled. Brief, page 4.

Claims 21 and 39 are illustrative of the claims on appeal and read as follows:

21. A device containing one or more polypeptides consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody.

39. A device containing one or more polypeptides selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, that specifically bind to an anti-*Ehrlichia* antibody.

The prior art references cited by the examiner are:

Rikihisa et al. (Rikihisa) WO 99/13720 Mar. 25, 1999

Waner, T, et al., "Comparison of a Clinic-based ELISA test kit with the Immunofluorescence test for the Assay of *Ehrlichia canis* antibodies in Dogs," Journal of Veterinary Diagnostic Investigation, Vol. 12, pp. 240-244 (2000)

Cadman, T. Et al., "Comparison of the Dot-Blot Enzymes Linked Immunoassay with Immunofluorescence for Detecting Antibodies to Ehrlichia canis ," The Veterinary Record, Vol. 135, pp. 362 (1994)

Grounds of Rejection

Claims 39-42 stand rejected under 35 U.S.C. 102(a), as anticipated by Waner.

Claims 21-24 and 39-42 stand rejected under 35 U.S.C. 102(b), as anticipated by Cadman.

Claims 21-24 stand rejected under stand rejected under 35 U.S.C. 102(b), as anticipated by Rikihisa.

We reverse these rejections.

Claim Grouping

For each rejection appellants do not argue individual claims separately. Brief, page 2. Therefore, we treat each statutory grounds of rejection separately, and select, as appropriate, claims 21 and 39 as representative of the claims on appeal for each relevant rejection. 37 C.F.R. § 1.192(c)(7)(2004), now 37 C.F.R. § 41.37(c)(1)(vii) (September 13, 2004).

DISCUSSION

Anticipation

Waner

Claims 39-42 are rejected under 35 U.S.C. 102(a) as anticipated by Waner.

According to the examiner (Answer, pages 4-5)

> Waner et al teach the use of a device (i.e. a clinic ELISA test kit). Waner et al teach that *Ehrlichia canis* IgG antibody titers of serum samples were determined by using a commercial ELISA test kit containing plastic combs sensitized with *E. canis* antigen. Waner et al teach that the sera to be tested was incubated with the comb (containing antigen dots). Waner et al teach that after washing away unbound antibodies the combs were allowed to react with goat anti-dog IgG alkaline phosphatase conjugate. Waner et al teach that bound antibodies were detected with a precipitating chromogen, 5-bromo-4chloro-3-indolyl phosphate and nitro-blue tetrazolium. The polypeptide sequence contained on the plastic comb (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. The instructions for performing various immunoassays (i.e. western blot, reversible flow

> chromatographic binding assay, enzyme linked immunosorbent assay or indirect immunofluorescense assay) are well known in the art. The device of Waner, et al appears to be the same as the claimed invention.
>
> Since the Office does not have the facilities for examining and comparing applicant's [sic] device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977)...

In response, Appellants argue (Brief, page 11)

> that Waner teaches whole *E. canis* proteins and cells and does not teach or suggest the use of any types of *E. chaffeensis* polypeptides in a device. SEQ ID NOs:3-7 of the present invention are *E. chaffeensis*-derived polypeptides (see Table 1 of specification) and therefore cannot be anticipated by Waner.
>
> Additionally, Waner does not teach or suggest the use of distinct polypeptides as shown in SEQ ID NOs:3-7. That is, Waner does not teach or suggest about 18 to about 20 amino acid polypeptides of SEQ ID NOs:3-7.

We agree with the Appellants that Waner does not describe the distinct polypeptides shown in SEQ ID NOs:3-7, as claimed. While the Examiner indicates that she is "interpreting the device to contain polypeptides that bind to anti-Erlichia antibody" (Answer, page 9), we do not agree that the claims before us should be so broadly interpreted. Claim 39 is directed to "a device containing one or more polypeptides selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, that specifically bind to an anti-Ehrlichia antibody." We agree that with the examiner that the device of claim 39 can include additional elements or ingredients due to the claim language "containing",

however, in our view, the polypeptides recited in claim 39 are limited to the specific polypeptide sequences recited in the claim. Thus, sequences longer than the specific polypeptide sequences recited in the claim, such as whole polypeptides that bind to anti-*Ehrlichia* antibody, are not within the scope of claim 39.

Waner teaches whole *E. canis* proteins and cells and does not teach any fragments of proteins or short polypeptides. Thus, in our view, the examiner has not provided sufficient evidence to shift the burden to appellants under the principles set forth in In re Best. As explained in Best, if the claimed and prior art products are identical or substantially identical, the USPTO can require an applicant to prove that the prior art product does not necessarily or inherently possess the characteristics of the claimed product. In order to invoke the principles of In re Best, the examiner must first make factual findings which support the conclusion that the claimed and prior art products prima facie are "identical or substantially identical." That determination must be made case-by-case based upon the facts in the individual case. In the present case the examiner has not made a sufficient factual finding that the claimed fragments are the same or substantially the same as a polypeptide disclosed in Waner to shift the burden of proof to appellants under the principles of Best.

The rejection of the claims for anticipation over Waner is reversed.

Cadman

Claims 21-24 and 39-42 are rejected under 35 U.S.C. 102(b) as anticipated by Cadman.

It is the examiner's position that (Answer, pages 5-6)

> Cadman et al teach a device (i.e. a cross dot blot apparatus), nitrocellulose paper coated with *E. canis* antigen. ... Cadman et al teach that test sera was incubated with the antigen (dots on nitrocellulose paper). Cadman et al teach that the bound antibody was detected with peroxidase-labeled goat anti-dog IgG and 4-chloronaphthol. The polypeptide sequence contained on the nitrocellulose membrane (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an Ehrlichia infection in a mammal in a diagnostic kit. ... The device of Cadman, et al appears to be the same as the claimed invention.

Appellants respond, arguing (Brief, page 15)

> that SEQ ID NOs:3-7 are derived from *E. chaffeensis* (see Table 1 of specification) and that Cadman does not teach any *E. chaffeensis* sequences. As such Cadman cannot anticipate devices containing SEQ ID NOs:3-7.
>
> Additionally, Cadman does not teach or suggest the use of distinct polypeptides as shown in SEQ ID N0s:1-7 and the claimed specified variants. That is, Cadman does not teach or suggest an about 18 to about 20 amino acid polypeptide of SEQ ID NO: 1-7 or the specified amino acid substitution variants recited in claims 21-24. Cadman teaches an IFA for *E. canis* that uses DH82 cells which are heavily infected with *E. canis* as an antigen. ... As such, Cadman teaches the use of whole *E. canis* infected cells or whole proteins purified from *E. canis* infected cells in the disclosed assays. Therefore, Cadman does not teach, suggest, or inherently disclose the specific, individual polypeptides shown in SEQ ID N0s:l-7 and does not identify the polypeptide fragments to be of any particular diagnostic use.

Again we agree with appellants that the examiner has not set forth a prima facie case of anticipation under the principles of In re Best to require a shift in the burden of proof to appellants to prove that the whole proteins of Cadman are not the

same as the 18-20 amino acid polypeptides recited in the device of claims 21 and 39. While appellants' claims encompass amino acid substitution variants (claim 21), they do not encompass amino acid addition or deletion mutants. Thus claim 21 does not encompass longer polypeptides than those recited therein.

The rejection of the claims for anticipation over Cadman is reversed.

Rikihisa

> Claims 21-24 are rejected under 35 U.S.C. 102(b) as anticipated by Rikihisa.
>
> Rikihisa et al teach devices such as columns, plastic dishes and membranes that contain the *Ehrlichia* polypeptides and peptide of the invention for using in serodiagnosing ehrlichiosis in mammals (see the Abstract and page 11). Rikihisa et al teach an amino acid variant of SEQ ID NO:7 has 85% identity to SEQ ID NO:7 (see Figure 19B). Rikihisa et al anticipates the claimed invention.

Answer, pages 6-7.

> Appellant argues (Brief, page 17) that
>
> [t]he Office Action incorrectly asserts that the claims are drawn to a composition and article of manufacture consisting essentially of an isolated polypeptide shown in SEQ ID N0s:1-7 and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody. The Office Action asserts that Rikihisa teaches an amino acid variant of SEQ ID NO:7 that has 85% identity to SEQ ID NO:7 and asserts that one of skill in the art could reasonably conclude that the Rikihisa *E.* canis polypeptides are variants of SEQ ID NO:7 since Rikihisa teaches that the invention embraces non-naturally occurring allelic forms or derivatives of outer membrane proteins. Rikihisa does not teach or suggest an element of the claims, that is, one or more polypeptides consisting of SEQ ID N0s:1-7. Therefore, the Rikihisa reference cannot anticipate the claims. The claims recite an *E. canis* polypeptide fragment.

In agreement with appellants, we find the examiner has not set forth a prima facie case of anticipation of the device of claim 21. Appellants' claims are directed to a device containing polypeptides which "consist of" specific polypeptides having specific lengths and specific amino acid sequences. Claim 21 does not use the language "consisting essentially of" as argued by the Examiner. Furthermore, as indicated in the Brief and at oral hearing, appellants' claim 21 is also directed to substitution variants of the specifically recited polypeptides, and not to deletion or addition variants. The examiner has not indicated, and we do not find where Rikihisa discloses one or more polypeptides "consisting of" SEQ ID N0s:1-7.

The rejection of the claims for anticipation in view of Rikihisa is reversed.

CONCLUSION

The rejections of the claims for anticipation in view of Waner, Cadman and Rikihisa are reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED

DEMETRA J. MILLS
Administrative Patent Judge

ERIC GRIMES
Administrative Patent Judge

LORA M. GREEN
Administrative Patent Judge

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